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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,364

09/06/2005

Dietmar Pennig

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30448

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03/18/2008

AKERMAN SENTERFITT

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EXAMINER

WOODALL, NICHOLAS W

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,364	Applicant(s) PENNING, DIETMAR	
	Examiner Nicholas Woodall	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-12,14 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-12,14 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/29/2008 has been entered.

Allowable Subject Matter

2. The indicated allowability of claims 13, 14, and 23 is withdrawn in view of the newly discovered reference(s) to Wagner (U.S. Publication 2004/0181228) and Kim (U.S. Patent 5,480,402). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-7, 13, and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (U.S. Patent 5,480,402) in view of Baumann (U.S. Patent 4,101,985) and Niiranen (U.S. Patent 6,692,498) and Wagner (U.S. Publication 2004/0181228).

Regarding claims 1 and 14, Kim discloses a device comprising a nail capable of being placed in a humeral shaft. The humeral nail includes at least one proximal transverse hole (40) and a screw (42) including a screw head and a screw body, wherein the at least one transverse hole comprises a couple of opposite holes on opposite walls of a cannulated nail. The intermediate plate element is in the form of a plate washer located between the screw head and the bone surface. The intermediate plate element is slightly bent. Kim discloses the invention as claimed except for the device further comprising at least one intermediate plate element inserted between the screw head and the bone surface, wherein the intermediate plate element comprises an enlarged flange portion and two elongated arm portions extending from the flange portion, the intermediate plate is slightly curved to adhere to the bone surface, and the at least one transverse hole having a partial internal thread and the screw having an outside diameter smaller than the diameter of the at least one transverse hole.

Baumann teaches a device further comprising at least one intermediate plate element including a slight curve in a longitudinal direction and having a substantially rounded profile in order to distribute stresses over a larger area of the bone surface. Wagner teaches a device comprising a bone fixation element including a transverse hole that has a partially threaded portion in order to engage and fix a threaded bone screw with respect to the bone fixation element (page 1 paragraph 009). Niiranen teaches an intermediate plate element that can be manufactured to any number of forms and sizes desired in order to best utilize the plate for the desired use of the plate (column 9 lines 23-50; claims 1, 3, 4, 7, 8, 11, 17, 18, 19, 21, and 22). Niiranen shows a plate element,

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such as a Y-shaped plate, that has elongated arms that are inherently capable of being placed astride of a screw and an elongated portion. The arms of the plate are shown to be substantially rounded. Niiranen teaches that the intermediate plate element may contain a plurality of holes in order to pass fasteners through the plate (column 9 lines 37-39; claims 4, 5, 6, 18, 19, and 20). Niiranen shows the holes passing through different areas of the plates including what would be the arms and enlarged portions of the Y-shaped plate. The Y-shaped plate is only an example of the shapes of plates Niiranen teaches. The examiner interprets Niiranen to include any number of plate shapes including C-shaped or U-shaped plates, which would also read upon the claim limitations for an open washer in the current application. It would have been obvious to one having ordinary skill in the art at the time of the invention to manufacture the invention of Kim further comprising at least one intermediate plate element in view of Baumann, the at least one transverse hole further including a partially threaded portion in view of Wagner, and wherein the intermediate plate element further includes the shapes and plurality of holes of the plates of Niiranen in order to distribute stresses over a larger area of the bone surface, to engage and fix a threaded bone screw with respect to a bone fixation element, and to best utilize the plate for the desired use and to allow the passage of fasteners through the plate.

Regarding claims 9 and 11, it would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the combination of Kim, Baumann, Wagner, and Niiranen to include a plurality of intermediate plate elements, since it has been held that mere duplication of the essential working parts of

a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claims 10 and 12, the combination of Kim, Baumann, Wagner, and Niiranen disclose the claimed invention except for the second intermediate plate element being larger than the first intermediate plate element and that the arms of the second intermediate plate element are larger than the arms of the first intermediate plate element. It would have been an obvious matter of design choice to make the second intermediate plate element and the arms of the plate larger in size than the first intermediate plate element and the arms of the plate, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In *re Rose*, 105 USPQ 237 (CCPA 1955).

Further regarding claim 14, the combination of Kim, Baumann, Wagner, and Niiranen disclose a device wherein both sides of the at least one transverse hole include a partial threaded portion.

Regarding claim 23, the combination of Kim, Baumann, Wagner, and Niiranen disclose a device inherently capable of being used by a method comprising the steps of producing an incision in the muscle surrounding the bone during a surgery phase to access a humeral fracture and inserting at least one intermediate plate element between the screw head and the bone cortex surface before the final fastening of the screw so that the head of the screw is abutting against the plate, wherein the intermediate plate element comprises an enlarged flange portion and two elongated arm

portions extending from the flange portion, the arm portions defining a longitudinal direction, wherein the intermediate plate element is slightly curved in the longitudinal direction to adhere substantially to the bone cortex surface, and wherein the elongated arm portions are positioned astride the screw body before the final fastening of the screw head.

Response to Arguments

6. The applicant did not provide any arguments in the after-final amendment received on 02/01/2008. The examiner has presented new grounds of rejection not necessitated by the amendment.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733